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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,460	11/24/2003	Shigeo Ohno	2352.002	6486

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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,460	OHNO, SHIGEO	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are presently pending.

Note to Applicant

Applicant is forewarned that the claims many errors and ambiguities that may severely hinder the prosecution of this case. For example, claim 15 contains the limitation "an SMG-1-acitivity-deficient [sic] mutant". Typically in the art, such would refer to a cell, but it is clear that Applicant is claiming the polypeptide from the disclosure of the specification. Such would necessarily obfuscate the prosecution history, and it is recommended that Applicant amend the claims to similarly more-accurately claim their invention. Further, certain claims, e.g., claim 11, have problems with multiple-dependency, and would not be examined unless amended to correct such errors.

While Applicant is allowed to claim the invention as they wish, the Examiner encourages Applicant to amend the claims to better distinctly claim the invention, prior to the Examiner's first action on the merits of the case.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 15-17, drawn to SMG-1 polypeptides and mutants thereof with altered activity, classified in class 435, subclass 183.

II. Claims 4-6, 8, and 17, drawn to polynucleotides encoding SMG-1 polypeptides, vectors comprising, and cells comprising the vector, as well as knock-out animals, classified in class 800, subclass 8.

III. Claim 7, drawn to antibodies to SMG-1 polypeptides, classified in class 530, subclass 387.1.

IV. Claim 9, drawn to a method for screening a substance which modifies an SMG-1 activity comprising determining if UFP1/SMG-2 is phosphorylated, classified in class 435, subclass 4.

V. Claim 10, drawn to a method to screen for a substance which modifies an SMG-1 activity, comprising analyzing whether an SMG-1 polypeptide is autophosphorylated, classified in class 435, subclass 4.

VI. Claims 11 and 13, drawn to a substance for suppressing nonsense mediated mRNA decay or treating and/or preventing a disease caused by premature translation termination, classified in class 514, subclass 1.

VII. Claims 12-15 and 16, drawn to an inhibitor of any PIK related kinase, classified in class 530, subclass 300.

VIII. Claim 15, drawn to an aminoglycoside antibiotic, classified in class 424, subclass 116.

IX. Claim 17, drawn to a substance which promotes an activity of SMG-1, classified in class 435, subclass 174.

X. Claim 18, drawn to an method to identify a nonsense mutation point in a gene, comprising analyzing the molecular weight of a protein, classified in class 435, subclass 4.

XI. Claim 19, drawn to a method for identifying a nonsense mutation point in a gene, comprising measuring a difference in an amount of mRNA derived from two different cell cultures, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV-V and X-XI are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and the different inventions contain different steps which provide for different modes of operation, and further due to such, require distinct considerations. To wit, invention IV requires determining if a Upf1/SMG-2 polypeptide has been phosphorylated by SMG-1, invention V requires determining if SMG-2 phosphorylates itself, invention X requires analyzing the molecular weight of a polypeptide, and invention XI requires analyzing detecting a difference in an amount of mRNA derived from two cell cultures. At least of each of these require distinct considerations with respect to search and examination, which would pose a serious burden on the examiner to search any two of these inventions together.

Inventions I-III and VI-IX are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, and have different structure which produce different function, each of which require distinct search and examination considerations. To wit, the polypeptides have amino acid sequence which

determine their function, and may be used to make antibodies or treat disease; the polynucleotides, vectors, and cells have a nucleotide structure which determines their function and ability to make transgenic animals or treat disease; the antibodies have a distinct structure from the polynucleotides, which may be used to detect the polynucleotide, or treat disease; the inhibitors of any PIK related kinase are disclosed to have the a structure unrelated to the polypeptides and antibodies in the specification, and may be used to treat different diseases; the antibiotics have a distinct structure from the other molecules and may be used to treat a different disorder: bacterial infection; and the substance which promotes and an activity of an SMG-1 polypeptide must necessarily have a distinct structure from the other molecules, as it increases the activity of one of the other groups, but may also be used to treat disease. Hence, due to the distinct structural and functional considerations, such would pose a serious burden on the examiner to search and examine any two groups together.

Inventions I-III and VI-IX are related as product and process of use to inventions IV-V and X-XI. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the various products have distinct uses, as delinated above, and as delineated in each of the methods claims. Moreover, due to the structural considerations, the search and examination burden on the Examiner to examine any two inventions together would be serious.

Moreover, while certain inventions are classified in single common broad classes, i.e., class 435, such class includes all molecular biology and microbiology. Hence, the search within

that broad class would be distinct for any single group, and would not necessarily produce art on any other class.

Because these inventions are distinct for the reasons given above and the search and examination required for any single group is distinct from that of any other group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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